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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/071,257

02/08/2002

Boyong Li

141-242A

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/071,257

Applicant(s)

LI ET AL.

Examiner

Micah-Paul Young

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment/Response dated 3/12/07.

#### *Claim Rejections - 35 USC § 102/103*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6,8-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wong et al (USPN 6,120,803 hereafter '803). The claims are drawn to a drug formulation comprises an extruded composition comprising a core wherein the core comprises an aminoketone antidepressant and a polymeric carrier. The dosage form also comprises a coating.
3. The '803 patent teaches a drug formulation comprising an extruded composition (col. 22, lin. 55-65), where the composition comprise antidepressants and carriers (col. 18, lin. 5-7). The antidepressants include bupropion a well-known aminoketone antidepressant (claim 6). The polymers composition can comprise multiple polymers such as hydroxypropylmethyl cellulose (claim 3), and hydroxypropylcellulose (preparation 1). The polymer can also be water insoluble such as ethylcellulose (col. 13, lin. 38-40). The formulation comprises an outer coating (Figure 7, part 11) that burst after being taken orally with food (col. 15, lin. 29-60). The tablet formulation is controlled in order to release in the gastric system of the patient (abstract), so the polymers should be insoluble in the pH below 7 (col. 13, lin. 50-55).

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4. Regarding the in vivo plasma profile it is the position of the Examiner that such limitations would be inherent to any formulation meeting the structural limitations of the instant invention. Since plasma profiles are determined by the physical characteristics of a dosage form such as the polymer types, concentration and configuration, along with the types and concentration of the particular drugs, it is the position of the Examiner that any dosage form meeting the physical limitations of the instant invention would also meet any in vivo plasma profiles claimed. The '803 patent teaches an extruded composition comprising a core which further comprises a carrier and at least one aminoketone antidepressant. The '803 patent further teaches the inclusion of each polymer claimed. Therefore it is the position of the Examiner that since each physical characteristic of the instantly claimed dosage form is met by the teachings of the '803 patent, the in vivo plasma profile is also met inherently. For these reasons at least the disclosures render the claims anticipated.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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As discussed above the '803 patent discloses an extruded controlled release dosage from comprising a core, which comprises a carrier and an aminoketone antidepressant. The '803 patent is however silent to the specific plasma profile. As discussed above this limitation would be an inherent feature of the instant invention. Further the plasma profile would have been obvious to one of ordinary skill in the art. Since the general conditions of the claims have been met by the '803 patent, specifically the same polymers and drugs are used in an identical formulation, any manipulation of these parameters would be obvious to one of ordinary skill in the art. Likewise results falling from this manipulation would be obvious to one of ordinary skill in the art. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

7. With these things in mind it would have been obvious to one of ordinary skill in the art to optimize the parameters of the '803 patent in order to achieve the desired plasma release rate since the patent discloses the same structural elements. It would have been obvious to optimize the component concentrations with an expected result of a controlled release formulation with improved release.

### ***Response to Arguments***

8. Applicant's arguments filed 3/12/07 have been fully considered but they are not persuasive. Applicant argues that:

- a. The '803 patent does not anticipate because it discloses a different C<sub>max</sub> value for a different compound.

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Regarding this argument it is the position of the Examiner that Applicant has ignored the disclosures of the '803 patent describing a formulation comprising aminoketone antidepressants (claim 6) and thereby ignores the disclosures that render the amended claim anticipated and obviated. The claims recite a plasma profile based off of a specific arrangement of polymers that according to the claims consist of a carrier in a core. This configuration is disclosed in the prior art, meaning the prior art must have the same properties since compounds and their properties cannot be separated. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

9. For these reasons the claims are inherently anticipated and obviated by the claims.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young

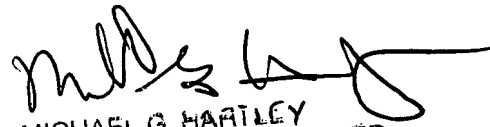
Application/Control Number: 10/071,257

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MP Young

Examiner  
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MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER